Research Ethics Application	
☐	**St. Joseph's Care Group (SJCG) REB** NEW **email address: SJCG_REO@tbh.net**
☐	**Thunder Bay Regional Health Sciences Centre (TBRHSC) REB** NEW **email address: TBR_REO@tbh.net**

For Office Use Only:
REB Number:
Submission Date:
Review Date:
Approval Date:

NOTE: **Boxes will not expand, so please use the space provided. If you require more space please reference the appropriate attachment, or section of the protocol / proposal. If you have any issues completing this form, please contact the appropriate Research Ethics Office**

Section A: Description of Research Team

Principal Investigator: The **Principal Investigator (PI)** is the individual responsible for the research. This may be someone internal or external to the organization(s).

Name:	Department and Institution:	Position:
Address:		
Phone:	Fax:	Email:

Best Contact Person for Project:	☐ same as PI	
Name:	Department and Institution:	Position:
Address:		
Phone:	Fax:	Email:

Section A: Description of Research Team (continued)

Research Team (list all co-investigators): If greater than 5 team members, append a list and submit with application

NOTE: Each additional team member is required to complete a Declaration of Conflict of Interest Form and append to this application.

Name:	Department and Institution:	Email:
Name:	Department and Institution:	Email:
Name:	Department and Institution:	Email:
Name:	Department and Institution:	Email:
Name:	Department and Institution:	Email:

Section B: Research Project/Protocol Title

Full Study Title:

Short Study Title:

Overall Description of Research Project/Protocol

Research Question: (In one sentence, state in question format)

Research Summary: In 300 words or less, in space provided [12 point Font], describe the goals of the overall research project in clear and simple language. Do not use technical language, jargon or acronyms.

Section C: Application Overview

If you require assistance in responding to these questions, please consult the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) website or the Research Ethics Office.

		Yes	No	Provide details:
a.	Does this research project involve organizations in addition to SJCG or TBHRSC?	☐	☐	List additional organizations:
b.	Does this research project require research ethics review elsewhere (other than SJCG & TBRHSC)?	☐	☐	Organization & status of application
c.	Has this research proposal/clinical protocol been peer-reviewed for scientific merit (e.g. CIHR, OMHF)?	☐	☐	☐ Copy attached
d.	Do you consider this research project to be low risk as defined by the TCPS 2?	☐	☐	
e.	Does this research involve participant recruitment from a vulnerable population as defined by the TCPS 2?	☐	☐	Identify group(s):
f.	Is this research in partial fulfillment of academic requirements [e.g., undergraduate, graduate, or postgraduate training]. (If "Yes", provide details)	☐	☐	Program, Supervisor & Institution:
g.	Has this project received the support for resources required to complete this project at SJCG and/or TBRHSC? (Attach required documentation as appendix)	☐	☐	Attached: ☐ TBRHSC Research Program ☐ SJCG organizational impact
h.	Does this research project require Joint Pharmacy & Therapeutics (P&T) approval?	☐	☐	Status (e.g., approved, submitted):
i.	Is there research funding associated with this project?	☐	☐	Specify:
	If yes, will either SJCG, TBRHSC/TBRRI administer any portion of the funding for this project (e.g., sign a contract or researchers agreement, required financial reporting)			Copy of contract/agreement attached: ☐ TBRHSC /TBRRI ☐ SJCG
j.	Is this an industry-sponsored research initiative? **Note:** A $3,000 review fee is charged for industry-sponsored protocols at the time of application.	☐	☐	Specify company:

Section D: Research Design & Methodology **(check the appropriate box by location, then provide details)**			
Design	SJCG	TBRHSC	Information obtained through other sites
Qualitative Methods	☐	☐	☐
Quantitative Methods	☐	☐	☐
Chart Review Only	☐	☐	☐
Clinical Trial/Medical Devices	☐	☐	☐
Please describe specific methodology:			

Section E: Local Implementation of Project Including Project Time lines (indicate for each organization)

In clear and simple language:

- Describe what aspects of the overall project are to be accomplished within each organization.
- Outline in detail the all steps required to accomplish the project by institution.
- Detail how the project will be customized / implemented for each site. Highlight if this differs from the protocol attached. Please be specific.

For SJCG: ☐ No involvement	Start Date: *(month day, year)*	End Date: *(month day, year)*
Provide details:		

Section E: Local Implementation of Project Including Project Time lines (indicate for each organization)		
For TBRHSC: ☐ No involvement	Start Date: *(month day, year)*	End Date: *(month day, year)*
Provide details:		

Section F: Recruitment of Participants Involved in the Research

		Yes	No
Does this research project involve direct participation of human participants?		☐	☐
Does this research project involve the review of health records (electronic & paper charts)?		☐	☐
Recruitment numbers		**SJCG**	**TBRHSC**
a.	Estimate the number of participants to be recruited at each site?		
b.	Estimate the number of individuals meeting eligibility criteria for study at each site?		
c.	Estimate the number of charts to be reviewed at each site?		
d.	Total number of participants to be recruited at **all** sites (global recruitment for multisite projects)? (including SJCG and/or TBRHSC and any other site totals)		
e.	Total number of charts to be reviewed at **all** sites (global recruitment for multisite projects)? (including SJCG and/or TBRHSC and any other site totals)		

Recruitment of participants and/or their information requires clear and locally appropriate strategies.
Describe **in detail**, the plans for recruitment and/or data collection for each organization.
What incentives are offered to participants, if any?

Recruitment strategy within SJCG:

Recruitment strategy with TBRHSC:

Section G: Informed Consent

Please provide a copy of all documentation to be used in the recruitment process. (e.g., information letters, consent forms, assent forms, promotional flyers).

	Consent Process	Yes	No
a.	Will informed consent be obtained from **all** participants directly?	☐	☐
b.	Are **all** participants capable of providing full and informed consent themselves?	☐	☐
c.	Do participants have the right to withdraw **at any time** during the research project?	☐	☐

Describe in detail the consent process.

Describe in detail how participants will be informed of their right to withdraw from the study. Consider withdrawal at all phases of the study.

Section H: Potential Benefits		Yes	No
a.	Are there potential benefits to participants?	☐	☐
b.	Are there potential benefits to the control group? ☐ no control group	☐	☐
c.	Are there potential benefits to the scientific community?	☐	☐
d.	Are there potential benefits to society?	☐	☐

Describe the proposed benefits to the participants, the scientific community and/or society that would justify asking participants to participate.

Section I: Potential Risks		Yes	No
a.	Are there any physical risks?	☐	☐
b.	Are there any psychological risks (e.g., embarrassed, worried or upset)?	☐	☐
c.	Are there any social risks (e.g., loss of status, privacy, and/or reputation)?	☐	☐
d.	Are there any financial risks?	☐	☐
e.	Will the participants be deceived in any way?	☐	☐
	➔ **If "Yes"**, will participants be debriefed? Debriefing is when a participant is informed they were deceived and why. (Provide details in the box below.)	☐	☐

If the answer is **"Yes" to <u>any</u> of the above questions in Section I**, please justify the methodology proposed indicating why alternative approaches involving less risk cannot be used.

Section J: Confidentiality

Describe the steps that will be taken to ensure confidentiality of the data. If confidentiality cannot be maintained, explain why not. Consult the guidelines for questions to consider.

Section K: Personal Health Information

NOTE: Principal Investigators are to ensure request for personal health information in accordance with the Personal Health Information Privacy Act [2004].

Access to **personal health information** is being requested from: (check the appropriate box)	SJCG	TBRHSC	Other sources
Human Participants	☐	☐	☐
Health Records (electronic or paper)	☐	☐	☐

Other: Please specify

Provide a description of the personal health information required from each site and the anticipated sources from which this information will be accessed. Attach surveys and/or data abstraction forms.

Section K: Personal Health Information

NOTE: Principal Investigators are to ensure request for personal health information in accordance with the Personal Health Information Privacy Act [2004].

Describe **the process** to ensure confidentiality/anonymity of health information. Include **who will have access** to the personal health information collected in the study, including position titles and credentials of this/these individual(s). Indicate if the access will be to identifiable or non-identifiable information. (use definitions as described in TCPS 2: Chapter 5)

Section L: Data Management and Storage

Describe data management, storage and security regarding information collected from either organization.

Section M: Funding Sources (copy of budget is required)

Please acknowledge all sources of funding/support to complete the project [e.g., internal TBRHSC/SJCG support, academic support (including student support), grants and industry-sponsored sponsorship or contracts]. Indicate which organization administers the funding. Attach/include a project budget broken down by organization (SJCG, TBRHSC, other organizations).

Section N: Declaration of Conflict of Interest for Principal Investigator

	Please note: Each additional project investigator is required to complete and sign a Declaration of Conflict of Interest Form to append to this application.	**Yes**	**No**
a.	Do you or your immediate family have any proprietary interests in the product under study or the outcome of the research including patents, trademarks, copyrights and licensing agreements?	☐	☐
b.	Do you or your immediate family members receive any compensation which is linked to the outcome of this study?	☐	☐
c.	Do you or your immediate family members have equity interest in the sponsoring company?	☐	☐
d.	Do you or your immediate family members receive payments of any kind from this sponsor (e.g., grants, compensation in the form of equipment or supplies, retainers for ongoing consultation or honoraria)?	☐	☐
e.	Are you or any member of your immediate family representatives on the sponsor's Board of Directors (or comparable body)?	☐	☐

If the answer is **"Yes" to <u>any</u> of the questions in Section N above**, please describe the arrangement and the implications of the potential conflict of interest, including the additional protections which have been put into place to protect study participants and/or information accessed.

Section O: Clinical Trial/Medical Devices Studies

This study is NOT a Clinical Trial: Skip Section O

This study is a Clinical Trial: complete Section O

REB review for this Clinical Trial is required to follow...		Yes	No	Details
a.	OHRP regulations?	☐	☐	
b.	FDA regulations?	☐	☐	

Provide status of required Clinical Trial documentation.		Completed	In progress	Not applicable	Details or attach documentation
c.	Registered with clinicaltrials.gov (provide #)	☐	☐	☐	
d.	Registered with another trial registry?	☐	☐	☐	
e.	Health Canada No Objection Letter?	☐	☐	☐	
f.	Health Canada Investigational Testing Authorization?	☐	☐	☐	
g.	Any other regulatory documentation? (list)	☐	☐	☐	
h.	Research team local credentials to conduct project?	☐	☐	☐	
i.	Data Safety Monitoring Board established?	☐	☐	☐	
j.	Is interim analysis planned for this study?	☐	☐	☐	
	Provide details				

Section P: List of Documentation for this application.

This list will be referenced in the approval letter, therefore be clear to identify all documents by title, appendix reference, version number and/or version date, as appropriate.

Document title	Title/Appendix Reference	version #	version date *(month day, year)*
REB application			

Section Q: Research Ethics Agreement

As the Principal Investigator:

- I agree to assume full responsibility for this study.
- I understand that any approval granted by the REB is limited to the information, activities and conditions as outlined within this application including all supporting documents (e.g., Information letters, consent forms). Any amendments and re-approval requirements will be submitted for approval by the REB prior to implementation.
- I agree to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Personal Health Information Privacy Act [2004] and any other regulations required by this specific protocol and, if applicable, the related funding agreement/contract.
- I have read and will conduct my research in accordance with the research policies and procedures specific for each organization to which I am applying, including all required notifications and renewals.
- I am aware of my responsibility to be familiar with and adhere to the standards outlined by my professional College and academic institution.
- I agree that all information received or exchanged as approved in the REB application will be held in strict confidence. Information disclosed will not be linked to other sources unless specified and approved by the REB.
- I will ensure all co-investigators and research personnel are provided training and demonstrate adequate understanding in the above referenced guidelines and regulations. I will ensure all co-investigators and research personnel have reviewed and demonstrate an understanding of the protocol and are in agreement with the implementation of the protocol at SJCG/TBHRSC as submitted to this Research Ethics Board (REB).
- I agree to provide access to all required documents for the purpose of monitoring and auditing by the REB, the sponsor and/or other appropriate regulatory authorities.
- I will not initiate research activities within SJCG/TBRHSC as outlined in this research ethics application until formal notification of approval has been received from all required REBs and, if required, related financial agreements/contracts.

The undersigned hereby agrees to these terms:

Principal Investigator's Signature:
(sign final hard copy after printing) _____

Print Name: _____

Date: [month day, year] _____

Please check the proper box for the following statement:	Yes	No
I agree to allow SJCG/TBRHSC to post my name, the full research title and the effective dates of the active study on their internal website for communication purposes. If you indicate "No", consult the appropriate Research Ethics Office at time of application.	☐	☐